Complete Summary

GUIDELINE TITLE

Urinary incontinence in women.

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Urinary incontinence in women. In: EBM Guidelines. Evidence-Based Medicine [CD-ROM]. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2005 Aug 31 [Various].

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Finnish Medical Society Duodecim. Urinary incontinence in women. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2005 Mar 31. Various p.

* * REGULATORY ALERT * *

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta (duloxetine hydrochloride), indicated for treatment of major depressive disorder and diabetic peripheral neuropathic pain. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with any hepatic insufficiency. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Urinary incontinence, including:

- Stress incontinence
- Urge incontinence
- Mixed incontinence

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Urology

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.

TARGET POPULATION

Women with urinary incontinence

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Diagnosis

1. Urine culture
2. Questionnaires (e.g., anamnestic questionnaire)
3. Pelvic examination and endoscopy, as indicated
4. Assess severity (e.g., severity index)
5. Specialized investigations (ultrasonography, radiography, urodynamics) as indicated

Treatment/Management

1. Conservative treatment
    - Weight reduction
    - Exercises to strengthen the muscles of pelvic floor
    - Bladder education (normalizing the micturition interval)
    - Pharmacologic management (e.g., duloxetine, anticholinergenic medication, local oestrogen therapy)
    - Electrical stimulation
2. Surgical therapy (e.g., colposuspension; tension-free vaginal tape [TVT]; trans-obturator tape [TOT]; operation aimed at enlarging the bladder) (See section on "Related Evidence" in the original guideline document for more information on surgical procedures.)
3. Patient education
    - Use of aids to prevent leaking
    - Pelvic floor muscle exercises

Interventions Considered But Not Specifically Recommended

1. Exercises with myofeedback
2. Preventive pelvic floor muscle training
3. Prompted voiding
4. Absorbent products
5. Adrenergic drugs
6. Abdominal retropubic suspension
7. Bladder neck needle suspension surgery
8. Periurethral injection of established manufactured bulking agents

MAJOR OUTCOMES CONSIDERED

- Change in incontinence episodes (e.g., number, frequency, volume)
- Side effects of medications
- Surgical complication rates
- Cost effectiveness
- Patient report and satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence reviewed was collected from the Cochrane database of systematic reviews and the Database of Abstracts of Reviews of Effectiveness (DARE). In addition, the Cochrane Library and medical journals were searched specifically for original publications.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
C. Limited research-based evidence. At least one adequate scientific study.
D. No research-based evidence. Expert panel evaluation of other information.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Tension-Free Vaginal Tape (TVT)

A technology assessment report summarizes in a systematic review that laparoscopic colposuspension and traditional slings have broadly similar cure rates

to TVT and open colposuspension, whereas injectable agents appear to have lower cure rates. TVT is less invasive than colposuspension and traditional sling procedures, and is also usually performed under regional or local anaesthesia. The principal operative complication is bladder perforation. Long-term effects (>2 years) are currently not known reliably. TVT was more likely to be considered cost-effective compared with the other surgical procedures.

Another technology assessment report summarizes in a systematic review that the surgical component of TVT is more expensive than colposuspension. However, there is a cost-saving per patient when accounting for the higher number of hospital bed-days associated with recovery from more invasive surgery. Perioperative complication rates of TVT have earlier been higher than in colposuspension, but in more recent studies complication rates are lower, perhaps owing to the greater experience of surgeons.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence [A-D] supporting the recommendations are defined at the end of the "Major Recommendations" field.

Basic Rule

- Differentiate between the two main types of incontinence: stress incontinence and urge incontinence

Types of Incontinence

1. Loss of urine on exertion (stress incontinence) is the problem in 3/4 of adult incontinent patients.
2. Urge incontinence is due to bladder dysfunction where the need to void is so sudden that loss of urine occurs before the patient makes it to the toilet. It occurs typically in elderly women after the menopause, but also in young women.
3. A combination of the two types is called mixed incontinence.
4. Other types of incontinence, such as overflow and reflex incontinence, rarely occur in women.

Epidemiology

- The prevalence in adult women (of 25 to 55 years of age) is about 20%. Every second patient conceals her problem.
    - The prevalence is 15% in women of 35, and 28% in women of 55.
- After retirement, about 50% of women suffer from urinary incontinence.

Aetiology

- In stress incontinence the pelvic floor may be weakened because of excessive body weight (>20% overweight), pregnancy, deliveries, and heavy work. Stress incontinence may also be caused by connective tissue weakness, asthma, or muscle-relaxant drug such as prazosin.
- Urge incontinence is a consequence of chronic bladder irritation. It can be related to
    - Sequelae of urinary tract infections
    - Past surgery for incontinence
    - Oestrogen deficiency after menopause
    - Diabetes or multiple sclerosis
    - Use of medicines, such as neuroleptics and diuretics
- In institutionalized patients, incontinence often is caused by cerebral ischaemia or dementia.
- Remember the possibility of overflow incontinence after surgery.

Investigations

- Exclude urinary tract infection by urine culture.
- A questionnaire differentiates fairly well between stress incontinence and urge incontinence.
- Exclude tumours of the pelvic region by pelvic examination (and endoscopy if required).
- An anamnestic questionnaire may be helpful in differentiating between stress and urge incontinence.
- The severity index, developed by Sandvik et al, is an easy and reliable way to assess the severity of the incontinence problem (Sandvik et al., 1993; Hanley, Capewell, & Hagen, 2001).
    - How often do you experience urine leakage?
        - 0 = never
        - 1 = less than once a month
        - 2 = one or several times a month
        - 3 = one or several times a week
        - 4 = every day and/or night
    - How much urine do you lose each time?
        - 1 = drops or little
        - 2 = more
    - The severity is described by the total score, which is the score for the first question multiplied by the score for the second question
        - 0 = no incontinence
        - 1-2 = slight
        - 3-4 = moderate
        - 6-8 = severe incontinence

Indications for Specialized Investigations (Ultrasonography, Radiography, Urodynamics)

- Annoying symptoms, especially if dominated by urge incontinence
- Recurrence of symptoms after surgery

Conservative Treatment

- Postmenopausal women with minimal symptoms should try local oestrogen therapy (a vaginal suppository or tablet once or twice a week) (Fantl, Cardozo, & McClish, 1994; Database of Abstracts of Reviews of Effectiveness [DARE]-953435, 1999; Zullo et al., 1998; DARE-983808, 2000) [B]. Local oestrogen is more effective than systemic oestrogen for either type of incontinence.
- Patients with mild stress incontinence
    - Weight reduction
    - Exercises for strengthening the muscles of the pelvic floor (Hay-Smith et al., 2001; Berghmans et al., 1998; DARE-981413, 2000) [A]
    - Duloxetine is a new pharmacological treatment option also for stress incontinence. It has been shown to reduce leakage episodes and to alleviate depression associated with leakage.
- Patients with mild urge incontinence
    - Bladder education (normalizing the micturition interval) (Wallace et al., 2004; Berghmans et al., 2000; DARE-20000524, 2001) [B]
    - Anticholinergic medication (Hay-Smith et al., 2002) [A] has been used.
        - The starting dose of oxybutynin is small (2.5–3 mg); the dose should be raised individually to the maximum of 5 mg x 3/day. The new slow release tablet (10 mg) taken once daily causes fewer side effects.
        - Tolterodine is as effective as oxybutynin in urge incontinence, but may have fewer anticholinergic side effects (dryness of the mouth and visual disturbances). The dose is 2 mg x 2 from the start. A slow-releasing form for single dosage (4 mg x 1) is also available.
        - Trospium chloride is one of the new drugs for urge incontinence. The dose is 20 mg x 1-2/day. The effect is at least equal to the other drugs but it may have even fewer side effects.
        - Solifenacin is the newest drug for urge incontinence, with benefits and harms equivalent to other drugs for this use.
- Electrical stimulation is worth trying in both types of incontinence (in stress incontinence the muscles of the pelvic floor are stimulated, in urge incontinence the overactivity of bladder muscles is decreased) (Bo, 1998; DARE-981604, 2000) [D].

Surgical Therapy

- Stress incontinence may be treated surgically according to the judgment of a urogynaecologist (Black & Downs, 1996).
    - Burch colposuspension was the "golden standard" up to the end of the 1990s (Burch, 1968). It can also be performed endoscopically quite easily either using a mesh or stitches.
    - The most widely used method today is a procedure where a meshlike tape is guided through a vaginal incision underneath the urethra like a

sling that remains in place without tension. Originally the loose ends of the tape were lifted through the abdominal wall and cut beneath the skin (TVT = tension-free vaginal tape) (Ulmsten, Johnson, & Rezapour, 1999). Nowadays the ends are passed through the obturator foramen (TOT, trans-obturator tape). The procedure may even be performed under local anaesthesia, and the results have been better than with Burch colposuspension (Valpas et al., 2004).

- In urge incontinence, surgery usually is not effective. In extreme cases, an operation aimed at enlarging the bladder may be indicated by a specialist.
- The treatment for mixed incontinence is selected according to the dominant type of incontinence.

Aids

- Aids: bandages, diapers, urinals, and plastic bed sheets prevent leaking. Vaginal bullets and cones (Herbison, Plevnik, & Mantle, 2002) [A], and vaginal tampons help to find the muscles in pelvic floor muscle training and prevent incontinence in short-lasting physical strain. A specialized nurse is responsible for supplying the aids and educating the patient.

Related Evidence

- Hysterectomy may increase the odds of developing incontinence up to 60% (Brown et al., 2000; DARE-20008541, 2001) [C].
- Exercises with myofeedback may be more effective than exercises alone for stress urinary incontinence, but the evidence is insufficient for reliable conclusions (De Kruif & Van Wegen, 1996; DARE-965250, 1999) [D].
- There is some evidence suggesting less urinary incontinence after preventive pelvic floor muscle training in childbearing women but the evidence is insufficient (Hay-Smith, Herbison, & Morkved, 2002) [C].
- There was some suggestive evidence that prompted voiding reduces incontinence episodes in the short term (Eustice, Roe, & Paterson, 2000) [C].
- There is not enough evidence to draw firm conclusions about the superiority of certain types of absorbent products (Brazzelli, Shirran, & Vale, 1999) [D].
- Adrenergic drugs appear to be more effective than placebo in reducing incontinence episodes and subjective symptoms (Alhasso et al., 2005) [B].
- Abdominal retropubic suspension appears to be better than anterior vaginal repair for subjective cure (Glazener & Cooper, 2001) [B].
- There is some evidence that laparoscopic colposuspension may have poorer results than open colposuspension. If laparoscopic colposuspension is performed, two paravaginal sutures appear to be more effective than one (Moehrer et al., 2000) [C].
- TVT procedure is at least as effective as colposuspension for the treatment of urodynamic stress incontinence and also appears to be a more cost-effective option. Long-term effects over 2 years are not reliably known (Bezerra, Bruschini, & Cody, 2005; Valpas et al., 2004; Ward & Hilton, 2004; Paraiso et al., 2005; Cody et al., 2003; "Tension-free vaginal tape," 2004 [A].
- Bladder neck needle suspension surgery is probably not as good as open abdominal retropubic suspension for the treatment of primary genuine stress urinary incontinence in terms of lower cure rates and higher morbidity (Glazener & Cooper, 2004) [C].

- Periurethral injection of established manufactured bulking agents appears to result in subjective and objective short term improvement of symptomatic female stress urinary incontinence in adults (Pickard et al., 2003) [C].
- Open retropubic colposuspension appears to be a more effective treatment modality for stress urinary incontinence than anterior colporrhaphy or needle suspensions, especially in the long term (Lapitan, Cody, & Grant, 2005) [B].

Definitions:

Levels of Evidence

A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
C. Limited research-based evidence. At least one adequate scientific study.
D. No research-based evidence. Expert panel evaluation of other information.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Concise summaries of scientific evidence attached to the individual guidelines are the unique feature of the Evidence-Based Medicine Guidelines. The evidence summaries allow the clinician to judge how well-founded the treatment recommendations are. The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

This guideline may help the clinician differentiate between types of incontinence in women and select appropriate interventions to reduce or eliminate symptoms of urinary incontinence.

Subgroups Most Likely to Benefit

Postmenopausal women are most likely to benefit from oestrogen therapy.

POTENTIAL HARMS

- Dry mouth is a common side effect of anticholinergic drug therapy.
- Published studies have reported that electrical stimulation produced side effects in about half of the women treated.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan 4 (revised 2005 Aug 31)

GUIDELINE DEVELOPER(S)

Finnish Medical Society Duodecim - Professional Association

SOURCE(S) OF FUNDING

Finnish Medical Society Duodecim

GUIDELINE COMMITTEE

Editorial Team of EBM Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Author: Juha Mäkinen

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Finnish Medical Society Duodecim. Urinary incontinence in women. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2005 Mar 31. Various p.

GUIDELINE AVAILABILITY

This guideline is included in a CD-ROM titled "EBM Guidelines. Evidence-Based Medicine" available from Duodecim Medical Publications, Ltd, PO Box 713, 00101 Helsinki, Finland; e-mail: info@ebm-guidelines.com; Web site: www.ebm-guidelines.com.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 17, 2002. The information was verified by the guideline developer as of February 7, 2003. This summary was updated by ECRI on April 2, 2004, October 5, 2004, February 22, 2005, June 10, 2005, and November 3, 2005. This summary was updated by ECRI on March 8, 2006, following the U.S. Food and Drug Administration advisory on Cymbalta (duloxetine hydrochloride).

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